

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

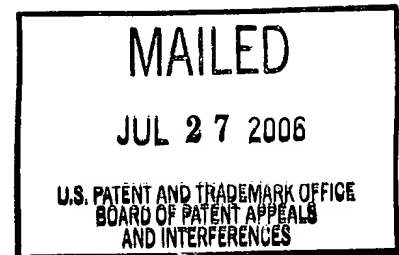
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte JAMES N. HERRON,
DOUGLAS A. CHRISTENSEN
and JACOB DURTSCHI

Appeal No. 2006-1563
Application No. 09/839,778

ON BRIEF



Before SCHEINER, MILLS, and LEOVITZ, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-21.

Claims 1, 2, 7, 8 and 10 read as follows:

1. A method for performing an assay, comprising:
substantially simultaneously evaluating the presence of a plurality of analytes in a sample, at least one analyte of the plurality of analytes having known parameters indicative of an acute metabolic or disease state;

substantially simultaneously determining concentrations of each of the plurality of analytes in the sample;

continuing the substantially simultaneous determination until the at least one analyte has been reliably determined to be present in an amount indicative of the

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metabolic or disease state; and

reporting said reliable determination of the presence of the plurality of analytes in an amount indicative of the metabolic or disease state.

2. The method according to claim 1, wherein evaluating the presence of at least one other analyte in the sample continues after the report of the reliable determination of an amount indicative of acute metabolic or disease state in order to accurately determine the presence or concentration of the at least one other analyte.

7. The method according to claim 4, wherein the continuation of the substantially simultaneous determination includes correlating a rate of reaction between the at least one analyte and the corresponding reactive element to a concentration of the at least one analyte.

8. The method according to claim 4, wherein the reactive elements are arranged in one or more patterns on a waveguide surface.

10. The method according to claim 9, wherein the light signal is indicative of a rate of reaction between the analyte of interest and the corresponding reactive element.

The prior art references cited by the examiner are:

Jackowski	5,747,274	May 5, 1998
Sawai et al. (Sawai)	4,224,304	Sept. 28, 1980

Grounds of Rejection

Claims 1-6, 8-9, and 13-21 stand rejected under 35 U.S.C. § 102(e) as anticipated by Jackowski.

Claims 7 and 10-12 stand rejected under 35 U.S.C. § 103(a) over Jackowski in view of Sawai.¹

We affirm these rejections.

¹ It is noted that a final rejection dated Dec. 29, 2003 contained a single rejection of the claims under 35 U.S.C. § 102. On November, 17, 2004, a new non-final rejection was issued adding the rejection under 103 over Jackowski in view of Sawai. Subsequently, Appellants filed a Second Appeal Brief dated February 17, 2005 (referred to as Brief, herein).

Claim Grouping

Appellants argue claims 1, 2 and 8 separately with respect to the 35 U.S.C. § 102 rejection. Appellants argue claim 10 separately with respect to the 35 U.S.C. § 103 rejection. We address each rejection and claim separately argued by appellants. 37 C.F.R. § 41.37(c)(1)(vii) (September 13, 2004).

DISCUSSION

Background

According to the specification, "[a]fter the onset of an acute myocardial infarction, the cardiac isoform of troponin I is measurable in the serum after four to six hours. Peak serum concentrations are reached after twelve to eighteen hours after the acute myocardial infarction. Unlike other cardiac markers (e.g. CK-MB and myoglobin), troponin I levels may remain elevated in the serum for several days before returning to normal. Because of these characteristics, the cardiac isoform of troponin I is used in the diagnosis of acute myocardial infarction." Specification, page 2.

Appellants claim a method for performing an assay which substantially simultaneously evaluates the presence of, and measures the concentration of, a plurality of analytes. While the specification does not provide a specific definition for the term "substantially simultaneously", the specification does state that "it has been found that reliable results can be obtained within about 1 to 2 minutes for positive specimens." Specification, page 4.

The specification further states that one embodiment of performing the assay involves a "detection means" which collects light from a "waveguide". Specification, page 16. Such detection means produces a signal and "[s]uch imaging signal collection provides simultaneous measurement of multiple samples in a much simpler way than a system in which a separate optical element is needed to read each well or patch." Specification, page 16.

Anticipation

Claims 1-6, 8-9, and 13-21 stand rejected under 35 U.S.C. § 102(e) as anticipated by Jackowski.

To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently. In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). The standard under § 102 is one of strict identity. "Under 35 U.S.C. § 102, every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim." Gechter v. Davidson, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997). "Every element of the claimed invention must be literally present, arranged as in the claim." Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

According to the examiner (Answer, page 3),

Jackowski discloses a method for performing an assay, comprising: substantially simultaneously evaluating the presence of a plurality of analytes in a sample, at least one analyte having known parameters indicative of an acute metabolic or disease state, see column 4, lines 32 - column 8, line 31, and column 19, lines 8-14; substantially simultaneously determining concentrations of each of the analytes, col. 29, lines 31-39;

continuing the determination until the analyte has been reliably determined to be present in an amount indicative of the metabolic or disease state, see column 29, lines 51-63; and reporting said determination in an amount indicative of the metabolic or disease state, see column 29, lines 51-63.

We agree that the specific portions of Jackowski pointed out by the examiner evidence and support a prima facie case of anticipation. For example, Jackowski states that (col. 8, line 57- col. 9, line 6),

in keeping with the temporal variability of patient conditions, the term "simultaneous" as it may apply to the performance of such a cardiac test and the retrieval of the results, for purposes of a diagnosis, is intended to refer to the ability to achieve such chemical diagnosis of chest pain within such shortened period, and therefore includes the measurement of the multiple analytes or markers ... whether performed within a single device having capabilities for such conjoint detection and measurement or by means of the use of individual such devices, each capable of detecting and indicating the presence and amount of a particular marker or analyte, provided that such detection and measurement are carried out within a period of time in which the detection and measurement of one analyte is meaningful with respect to the other analytes detected and measured.

Jackowski further describes the use of a troponin I cardiac marker. Col. 17, Tables 2 and 3. In sum, Jackowski describes a method for the diagnosis of chest pain using multiple analytes or markers, wherein the method measures the presence and amount of an analyte, and indicates that such measurements are performed simultaneously.

Appellants did not specifically define the term "simultaneously" in the specification. During ex parte prosecution, claims are to be given their broadest reasonable interpretation consistent with the description of the invention in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

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The Federal Circuit has also repeatedly rejected the contention that depiction of a single embodiment in a patent necessarily limits the claims to that depicted scope. See Phillips v. AWH Corp., 415 F.3d 1303, 1323, 75 USPQ2d 1321, 1334 (Fed. Cir. 2005). See, also Agfa Corporation v. Creo Products Inc. (Fed. Cir., 05-1079, 6/26/2006).

Therefore, we do not read the exemplified time frame of the assay of one to two minutes from the specification into the claims.

In our view, when the claims are interpreted consistently with the specification and given their broadest reasonable interpretation, appellants' claim term "substantially simultaneously" reads on Jackowski's definition of simultaneous, i.e., a shortened period of time.

In response, appellants argue that, in Jackowski, "the term 'simultaneous' is not used... to indicate that analysis of different analytes occurs concurrently, but that the analysis occurs within a given period of time." Brief, page 8. Thus appellants argue that Jackowski is limited to determinations that occur at "different points in time" that correspond to different assays conducted on different parts of a single sample. Id.

The examiner finds, however, that "the term 'simultaneous' as used by Jackowski encompasses a concurrent evaluation of the sample, because Jackowski indicates that the term 'simultaneous' includes an evaluation within a given period of time (col. 22, lines 8-9), and a concurrent evaluation is within a given period of time" and does not exclude concurrent analysis. Answer, page 7. In agreement with the Examiner, we note that the claims before us do not require concurrent evaluation, they require

"substantially simultaneous" evaluation.

Appellants further argue that "Jackowski neither expressly nor inherently describes 'continuing a substantially simultaneous determination' of the presence of one analyte in a sample 'until the at least one analyte has been reliably determined to be present in an amount indicative of a metabolic or disease state...'." Brief, page 9. According to appellants, "the term 'continuing' in independent claim 1 clearly indicates that analysis of the binding of at least one analyte occurs over a period of time rather than at a single point in time." Again, we find no clear definition or explanation in the specification of the term "continuing". We interpret the term to have its ordinary meaning, "to go on with a particular action".² Thus, the claimed assay is interpreted as "continuing" until at least one analyte has been reliably determined to be present in an amount indicative of the metabolic or disease state. See also, specification, page 25. Jackowski continues the disclosed assay until the presence and amount of an analyte is detected, and provides an "effective" "test to achieve a biochemical diagnosis within a short period of time." Jackowski, Col. 8, lines 54-56.

The examiner also argues that, in contrast to appellants' claim interpretation (Brief, page 9), claim 1 "does not require that the kinetics of the binding reactions be evaluated to provide an accurate determination of the presence, and optionally the amount of an analyte." Answer, page 9. We agree with the examiner that claim 1 merely requires that the assay "continues" until there is a reliable result based upon a single analyte and does not exclude the assay disclosed by Jackowski.

² Webster's II New Riverside Dictionary, Riverside Publishing Co, Boston, MA, 1994, p. 305.

The examiner further points out that Jackowski specifically states that its assay detects and indicates the "presence and amount of a particular marker or analyte, provided that such detection and measurement are carried out within a period of time in which the detection and measurement of one analyte is meaningful with respect to the other analytes detected and measured." Col. 9, lines 1-5. Jackowski additionally states that the "method comprises detecting and measuring at least three markers associated with cardiac disorder simultaneously..." Col. 9., lines 37-39. Thus, we agree with the examiner that "Jackowski teaches continuing the assay over a period of time until an analyte has been determined to be present in an amount indicative of a disease state." Answer, page 10.

As to claim 2, the examiner argues that the step of continuing the evaluation of the presence of at least one other analyte after the report in order to accurately determine the presence or concentration of the analyte is described at column 22, lines 1-12 of Jackowski. Id. Appellant argues that the description of Jackowski is limited to "effecting evaluations of the presence of analytes in a sample at single points in time, rather than continuously." Brief, page 10. As indicated above, Jackowski teaches that their assay is conducted over a period of time and that the level of each marker simultaneously present in the sample will be assessed to yield meaningful data. Col. 22, line 19. Therefore, we are not persuaded by appellants' argument.

With regard to claim 8, the examiner argues that Jackowski describes that the "reactive elements are arranged in a pattern on the waveguide surface", (col. 30, line

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67, col. 31, lines 8-9, and lines 15-16, see figure 10, disclosing the arrangement of the antibodies, i.e., reactive elements.)" Answer, page 4. Appellants argue that this embodiment is not disclosed by Jackowski, but fail to specifically point out the defect in the examiner's arguments. Thus, we are not persuaded by appellants' arguments with respect to Claim 8.

We find the examiner has presented evidence to support a prima facie case of anticipation which has not been convincingly rebutted by appellants. The rejection of the claims for anticipation is affirmed.

Obviousness

Claims 7 and 10-12 stand rejected under 35 U.S.C. § 103(a) over Jackowski in view of Sawai. We select claim 10 as a representative claim for purposes of this rejection.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A prima facie case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art. In re Bell, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993). An obviousness analysis requires that the prior art both suggest the claimed subject matter and reveal a reasonable expectation of success to one reasonably skilled in the art. In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991). With this as background, we analyze

the prior art applied by the examiner in the rejection of the claims on appeal.

According to the examiner (Answer, page 5)

Jackowski provides several examples of methods to determine the extent or amount of binding between the antibodies and markers (see for example, col. 28, lines 8-38.) Jackowski teaches that other methods for determining the presence and amount of a marker or analyte may be used in the invention (col. 29, lines 31-36).

However, Jackowski does not disclose that the continuation step includes correlating a rate of reaction between the analyte and the reactive element to a concentration of the analyte (claims 7 and 12); nor that the light signal is indicative of a rate of reaction between the analyte of interest and the reactive element (claims 10 and 11).

The examiner relies on Sawai for the disclosure of a method for the "quantitative determination of antigens in a sample by evaluating the rate of increase in absorbance or percent absorption per unit time (col. 11, lines 36-44). This method is a method of correlating a rate of reaction between the analyte and the reactive element to a concentration of the analyte, as well as a method wherein the light signal is indicative of a rate of reaction between the analyte and the reactive element..." Answer, page 6.

The examiner concludes "[i]t would have been obvious to one of ordinary skill in the art ... to utilize the Sawai method as the method of determining the amount of analyte binding that is generally taught by Jackowski because Sawai teaches that it is a known method for determining the extent or amount of binding (and Jackowski teaches that known methods for determining binding may be used.)" Id.

In response, appellants reiterate and add to their original argument, alleging that, "neither Jackowski nor Sawai teaches or suggests a technique for assaying a sample for multiple analytes *simultaneously*." Brief, page 13. This argument of appellants

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was previously addressed with respect to Jackowski, herein. We concluded, based on the record and claims before us, that Jackowski discloses a technique for assaying a sample for multiple analytes *simultaneously*. We find no additional specific statement with respect to the disclosure of Sawai. While appellants make a general argument there is no motivation to combine Jackowski and Sawai (Brief, page 13), appellants fail to specifically address or find fault with the examiner's indicated motivation to combine the cited references.

Appellants argue that Jackowski and Sawai fail to disclose "stimulating a light signal from a reactive element, which is indicative of a rate of reaction between the analyte of interest and the type of reactive element from which the light signal is stimulated", as required by claim 10. Brief, page 13. The Examiner finds Sawai discloses "a method for quantitative determination of antigens in a sample by evaluating the rate of increase in absorbance or percent absorption per unit time." Col. 11, lines 36-44. Answer, page 12. The appellants fail to address the examiner's arguments, either in the Brief or Reply Brief. Therefore, we affirm the rejection of claim 10. Claims 7 and 11-12, fall with claim 10.

We find the examiner has provided sufficient evidence to support a prima facie case of obviousness which remains un rebutted by appellants. In view of the above, the


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rejection of the claims for obviousness over Jackowski in view of Sawai is affirmed.

CONCLUSION

The rejection of claims 1-6, 8-9, and 13-21 under 35 U.S.C. § 102(b) as anticipated by Jackowski is affirmed. The rejection of claims 7 and 10-12 under 35 U.S.C. § 103(a) over Jackowski in view of Sawai is affirmed.

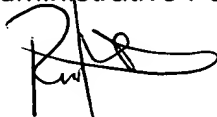
AFFIRMED



Toni R. Scheiner
Administrative Patent Judge



Demetra J. Mills
Administrative Patent Judge



Richard M. Lebovitz
Administrative Patent Judge

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